I hereby certify that this paper is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 596704245 US, on the date shown below in a box addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: October 31, 2007

Signature:

Imac Mediano)

Patent Docket No. 420052000126

OCT 3 1 2007 W

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Neil P. DESAI et al.

Serial No.:

09/446,783

Int'l Filing Date: June 26, 1998

For:

NOVEL FORMULATIONS OF PHARMACOLOGICAL AGENTS, METHODS FOR THE PREPARATION THEREOF AND METHODS FOR THE

**USE THEREOF** 

Examiner:

J. Vu

Group Art Unit:

1618

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

For the Examiner's convenience, Applicants have grouped certain documents on the attached Form PTO/SB08a/b into the categories outlined below.

Document Nos. 1-42, 79-80, 82-83, 85, 89, 91, 96, 98, 101-102, 104-105, 108, 123, 139, 140, 143, 147-148, 191, 193-194, 196, and 203-204 provide patents and patent applications having common inventor(s) with the instant application. Among these, Documents 1-15, 17-42, 79-80, 82-

pa-1196345

83, 85, 89, 96, 98, 102, 104, 105, 123, 139, 140, 143, 147-148, 196, and 203-204 are owned by owner of the instant application.

Document Nos. 43, 46, 50, 51, 55, 60, 78, 81, 87, 94, 95, 99, 106-107, 113, 115, 122, 133, 155, 162, 163, 165, 170, 172, 179-180, 189-190, 195, 199, 201, 206, 220, 236, and 238 provide references cited in office actions or search reports during prosecution of cases related to the instant application.

Document Nos. 205, 211, 212, 214-217, 225, 226, and 243 provide references describing certain aspects of the invention. Among these, Document Nos. 205, 211, and 243 are published after the filing date of the instant application.

Regarding commonly-owned U.S. Pub. No. 2007/0020337 (Document No. 25), the Examiner's attention is directed to  $\P$  [0007]-[0011] and [0022]. Regarding commonly-owned U.S. Pub. No. 2006/0121119 (Document No. 21), the Examiner's attention is directed to  $\P$  [0004]-[0010], [0013]-[0015], [0024] and [0039].

Document No. 249 is a decision of United States District Court for the Central District of California related to U.S. Patent No. 6,096,331, to which the present application claims priority.

This Supplemental Information Disclosure Statement is submitted:

	With the application; accordingly, no fee or separate requirements are required.
$\boxtimes$	Before the mailing of a first Office Action after the filing of a Request for Continued
	Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97
	(e)(1) has been provided.
	Within three months of the application filing date or before mailing of a first Office Action
	on the merits; accordingly, no fee or separate requirements are required. However, if
	applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
	After receipt of a first Office Action on the merits but before mailing of a final Office Action
	or Notice of Allowance.
	A fee is required. A check in the amount of is enclosed.

	A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to	
	this submission in duplicate.	
	A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is	
	believed to be due.	
After mailing of a final Office Action or Notice of Allowance, but before payment of the		
issue fee.		
	A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the	
	amount of is enclosed.	
	A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal	
	form (PTO/SB/17 is attached to this submission in duplicate.)	

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other

fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing <u>420052000126</u>.

Dated: October 31, 2007

Respectfully submitted,

Alicia J. Hager

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